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In the Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE

Respondent.

On Petition for a Writ of Certiorari to the Vermont Supreme Court

BRIEF OF *AMICI CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND U.S. CHAMBER OF COMMERCE IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTEREST OF THE *AMICI CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 2

ARGUMENT 3

I. The Decision Below Thwarts Important Federal Policy By Erroneously Denying Preemptive Effect To The FDA's Approval Of Petitioner's Drug Label 3

A. State-law failure-to-warn liability conflicts with the FDA's goals of preventing overwarning and patchwork regulation 4

B. The decision below misconstrues the FDCA and the relevant regulation promulgated thereunder 10

II. The Decision Below Conflicts With This Court's Precedent 13

A. The decision below conflicts with this Court's decisions concerning the deference due executive agencies 13

B. The decision below conflicts with this Court's decisions concerning the effect of savings clauses on implied preemption 16

III. This Case Is An Appropriate Vehicle For Resolving A Recurring Conflict In The Lower Courts On An Important Issue Of Federal Statutory Interpretation 18

A. Certiorari should be granted in this case 18

TABLE OF CONTENTS—continued

Page

B. At minimum, this Court should call for the views of the Solicitor General 20

CONCLUSION 20

TABLE OF AUTHORITIES

Page(s)

CASES

Auer v. *Robbins*, 519 U.S. 452 (1997) 15

In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) 18

Brochu v. *Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981) 19

Brooks v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) 7, 8, 9, 10

Caraker v. *Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001) 18

Cartwright v. *Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005) 18

Chevron U.S.A., Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) 14, 16

Chicago & N.W. Transp. Co. v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981) 13

Christensen v. *Harris County*, 529 U.S. 576 (2000) 14, 15

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 10

Colacicco v. *Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) 4, 5, 6, 19

Dusek v. *Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) 18

Ehlis v. *Shire Richwood, Inc.*, 233 F. Supp. 2d 1189 (D.N.D. 2002) 18

Fidelity Fed. Sav. & Loan Ass'n v. *de la Cuesta*, 458 U.S. 141 (1982) 13

Geier v. *American Honda Motor Co.*, 529 U.S. 861 (2000) 2, 13, 15, 17

TABLE OF AUTHORITIES—continued

Page(s)

Hillsborough County v. *Automated Med. Labs., Inc.*, 471 U.S. 707 (1985) 14, 15

Horn v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) 7

Laisure-Radke v. *Par Pharm., Inc.*, 2006 WL 901657 (W.D. Wash. Mar. 29, 2006) 18

Martin v. *Occupational Safety & Health Review Comm'n*, 499 U.S. 144 (1991) 15

Mazur v. *Merck & Co.*, 742 F. Supp. 239 (E.D. Pa. 1990) 18

McNellis v. *Pfizer, Inc.*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006) 19

Needleman v. *Pfizer, Inc.*, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004) 18

Peters v. *Astrazeneca, LP*, 417 F. Supp. 2d 1051 (W.D. Wis. 2006) 18

Salmon v. *Parke-Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975) 19

Sinnot v. *Davenport*, 63 U.S. (22 How.) 227 (1859) 17

Sykes v. *Glaxo-SmithKline*, 2007 WL 957337 (E.D. Pa. Mar. 28, 2007) 18

In re Tetracycline Cases, 747 F. Supp. 543 (W.D. Mo. 1989) 19

United States v. *Locke*, 529 U.S. 89 (2000) 2, 14

Witczak v. *Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005) 18

Zikis v. *Pfizer, Inc.*, 2005 WL 1126909 (N.D. Ill. May 9, 2005) 18

TABLE OF AUTHORITIES—continued

Page(s)

STATUTES, RULES AND REGULATIONS

21 C.F.R. § 201.57(e) 4

21 C.F.R. § 314.70(c) 11, 16

21 U.S.C. § 331 12

21 U.S.C. § 333 12

21 U.S.C. § 352 12

21 U.S.C. § 393(b)(2) 15

Drug Amendments of 1962 § 202, Pub. L. 87-781, 76 Stat. 780 (1962) 16, 17

New Drug and Antibiotic Regulations, 47 Fed. Reg. 46622 (Oct. 19, 1982) 11

New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452 (Feb. 22, 1985) 4

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) ..... *passim*

U.S. CONST. art. VI, cl. 2 13

MISCELLANEOUS

150 Cong. Rec. E1505 (July 22, 2004) 7

150 Cong. Rec. H5598-5599 (July 13, 2004) 6

150 Cong. Rec. S8657 (daily ed. July 22, 2004) 6, 7

Amicus Curiae Brief of the United States of America, *Dowhal* v. *SmithKline Beecham Consumer Healthcare, LP*, 56 P.3d 1027 (Cal. 2003) (No. A094460), 2003 WL 23527781 6

Amicus Curiae Brief of the United States, *In re Paxil Litig.*, 2002 WL 31375497 (C.D. Cal. Sept. 5, 2002) (No. CV 01-07937 MRP) 6, 9, 10

TABLE OF AUTHORITIES—continued

Page(s)

Brief for *Amicus Curiae* the United States of America, *Colacicco* v. *Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-CV-05500-MMB), 2006 WL 1724170 ..... 4, 5

Brief for *Amicus Curiae* the United States of America, *Motus* v. *Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372 & 02-55498), 2002 WL 32303084 ..... 5, 6

Corrected *Amicus* Brief for the United States, *Kallas* v. *Pfizer, Inc.*, No. 2:04CV0998 PGC (N.J. Sup. Ct. 2005), 2005 WL 4030146 6

H.R. REP. NO. 853 (1976) 10

James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265 (1990) 8

Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" From the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293 (1994) 12

Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167 (2000) 8

Statement of Interest of the United States, *Bernhardt* v. *Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000) (No. 00 Civ. 4042 LLM) 6

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND U.S. CHAMBER OF COMMERCE AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*

Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 125 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of the law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Since 1983, PLAC has filed over 725 briefs as *amicus curiae* in both state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. Appendix A lists PLAC's corporate members.

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the nation's business community.[1]

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[1] Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. The parties' letters consenting to the filing of this brief have been filed with the Clerk's office.

PLAC and the Chamber—which have filed *amicus* briefs in prior preemption cases, including *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), and *United States* v. *Locke*, 529 U.S. 89 (2000)—are well situated to address the issue of preemption raised in this case. Their members are engaged in commerce in each of the 50 states and are subject in varying degrees to a wide range of federal regulations. As a result, their members often confront the interplay between the duties imposed by federal law and the state common-law standards applied in product liability cases. Therefore, they not only are uniquely suited to offer a broader perspective on preemption than the parties may provide, but also are keenly interested in ensuring that the regulatory environment in which their members operate is a rational and consistent one.

INTRODUCTION AND SUMMARY OF ARGUMENT

Although this case arises in the context of federal drug regulation, its significance extends far beyond the pharmaceutical industry. If the decision below is allowed to stand, all manufacturers of federally regulated products, regardless of industry, will be at risk of having to choose between complying with federal law or complying with state law. If they decide to comply with federal law, they will—like the petitioner in this case—be exposed to multimillion dollar state-law tort liability. No company should be forced to make that choice or to suffer those consequences.

In addition to being fundamentally unfair, the decision below impedes interstate commerce and threatens the proper functioning of the federal regulatory system. In allowing private litigants to hold manufacturers liable under state law for failing to include risk warnings that are contrary to those mandated by the relevant federal agency, the Vermont Supreme Court—expressly disregarding the agency's views—misconstrued federal statutes and misapplied this Court's precedent. The results are potentially devastating. Permitting juries in individual cases to substitute their *ad hoc* conclusions for those reached by an expert federal agency can easily

upset the delicate regulatory balance struck by that agency after comprehensive review and careful consideration of all available scientific information.

Unfortunately, the Vermont Supreme Court is not alone in its error. Although some courts have correctly concluded that approval of a drug label by the Food and Drug Administration preempts state-law failure-to-warn claims, many others have reached the opposite, erroneous conclusion. Like the court below, they have failed to give due deference to the FDA's authoritative interpretation of the Food, Drug and Cosmetic Act ("FDCA"). As a result, the public health has been endangered and the goal of national uniformity in drug regulation has been undermined.

It is vitally important that this Court grant certiorari to vindicate the Supremacy Clause and to resolve the dangerous split in lower court authority.

ARGUMENT

I. The Decision Below Thwarts Important Federal Policy By Erroneously Denying Preemptive Effect To The FDA's Approval Of Petitioner's Drug Label.

The FDA is the expert federal agency charged by Congress with ensuring that drugs are safe and effective. To that end, the FDCA mandates that drug manufacturers obtain FDA approval to market prescription drugs. The agency decides whether to approve a drug based "on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested *in the labeling*." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("Preemption Preamble") (citing 21 U.S.C. § 355(d)) (emphasis added). Indeed,

> [t]he *centerpiece* of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evi-

> dence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such *labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use.*

Ibid. (emphasis added); see also *id.* at 3967–3969; New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985) ("Drug labeling serves as the standard under which FDA determines whether a product is safe and effective."). By imposing state-law tort liability on a drug manufacturer despite the manufacturer's compliance with FDA labeling directives, the decision below "threaten[s] FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." 71 Fed. Reg. at 3935.

A. State-law failure-to-warn liability conflicts with the FDA's goals of preventing overwarning and patchwork regulation.

The FDA's overarching goal in regulating the warning labels of pharmaceuticals is to strike the right balance between providing sufficient information to drug users and providing too many, or the wrong kind of, warnings. "FDA seeks to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence of an association between a drug and a particular hazard before warning of that association on a drug's labeling." Brief for *Amicus Curiae* the United States of America at 14, *Colacicco* v. *Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-CV-05500-MMB), 2006 WL 1724170 (citing 21 C.F.R. § 201.57(e)) ("FDA *Colacicco* Br."). To achieve that goal, "FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to use of the

product in day-to-day clinical practice." 71 Fed. Reg. at 3968. Through careful consideration of these factors, "appropriate warnings are drafted that identify established risks while avoiding inadequately substantiated risks, mention of which could improperly deter use of the drug to the detriment of the very patients it is designed to benefit." FDA *Colacicco* Br. 5.

In the Preemption Preamble, the FDA emphasized how delicate and important this balance is, and how overwarning can harm patients and interfere with regulatory goals:

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.

71 Fed. Reg. at 3935; *accord* FDA *Colacicco* Br. at 13 ("In considering the agency's views on drug labeling, it is critical to understand that, where warnings are concerned, more is not always better."). Among other dangers, "[e]xaggeration of risk could discourage appropriate use of a beneficial drug." 71 Fed. Reg. at 3935. Moreover, "labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance.'" *Ibid.* (quoting 44 Fed. Reg. 37,434, 37,447 (June 26, 1979)). Thus, "State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act." *Ibid.*; see also, *e.g.*, Brief for *Amicus Curiae* the United States of America at 23–24, *Motus* v. *Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372 & 02-55498), 2002 WL 32303084 (explaining that "[u]nder-utilization of a drug

based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects").[2]

These concerns were echoed not long ago in a letter entered in the *Congressional Record* from five former Chief Counsel of the FDA, whose tenures date back to 1972. That letter debunked allegations that the FDA had gone "'in a radical new direction'" by arguing in its *amicus* brief in *Motus* that failure-to-warn claims are preempted by the FDCA. 150 Cong. Rec. S8657 (daily ed. July 22, 2004) (quoting 150 Cong. Rec. H5598-5599 (July 13, 2004)); *accord* 150 Cong. Rec. E1505 (July 22, 2004). These former FDA Chief Counsel, who served in both Republican and Democratic administrations, explained that, in arguing for preemption, the

[2] The briefs filed by the FDA in *Colacicco* and *Motus* are just two of the numerous *amicus* briefs supporting implied preemption filed by the FDA since 2000. In each case in which it has filed an *amicus* brief, the FDA was concerned about some aspect of civil litigation that posed a specific threat to its authority. See, *e.g.*, Corrected *Amicus* Brief for the United States, *Kallas* v. *Pfizer, Inc.*, No. 2:04CV0998 PGC (N.J. Sup. Ct. 2005), 2005 WL 4030146 (arguing that failure-to-warn claim was preempted by FDA rejection of scientific basis for warning); *Amicus Curiae* Brief of the United States of America, *Dowhal* v. *SmithKline Beecham Consumer Healthcare, LP*, 56 P.3d 1027 (Cal. 2003) (No. A094460), 2003 WL 23527781 (state-mandated statement on smoking cessation product preempted where FDA had concluded that statement should not appear); *Amicus Curiae* Brief of the United States, *In re Paxil Litig.*, No. CV 01-07937 MRP (C.D. Cal. Sept. 5, 2002) (state-law injunction against FDA-approved advertising preempted); Statement of Interest of the United States, *Bernhardt* v. *Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000) (No. 00 Civ. 4042 LLM) (state-law injunctive relief to force changes in drug labeling and issuance of "Dear Doctor" letters preempted).

"amicus curiae briefs filed by [the United States] * * * protect FDA's jurisdiction and the integrity of the federal regulatory process" because, "[i]f every state judge and jury could fashion their own labeling requirements for drugs and medical devices, there would be regulatory chaos for these two industries that are so vital to the public health, and FDA's ability to advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded." 150 Cong. Rec. S8657.

Courts and commentators alike have acknowledged the wisdom of preserving FDA primacy in reviewing and approving labeling for products over which it has regulatory authority. When the Third Circuit held in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), that the FDA's premarket approval process for medical devices preempts state common law claims alleging defective design and manufacture, the court relied upon the agency's conclusion that "'State common law tort actions threaten the statutory framework for the regulation of medical devices, *particularly with regard to FDA's review and approval of product labeling.*'" *Id.* at 178 (quoting the Letter Brief of *Amicus Curiae* the United States of America at 25) (emphasis added). Similarly, in *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc), *cert. denied*, 535 U.S. 1056 (2002)—a failure-to-warn case involving the labeling of a medical device approved by the FDA—the Eighth Circuit identified

> a number of sound reasons why the FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks. A label with many varied warnings may not deliver the desired information to users. Space on product labeling material is also a factor, and the most effective labels are those with large, bold warnings and a simple design.

Id. at 796.

None of these concerns is likely, however, to motivate—or even be considered by—a jury that is asked to decide a state failure-to-warn claim. All that such a jury would be called upon to determine is whether the content of the defendant's label satisfied the defendant's state-law duty to warn of the *particular* risk encountered by the *particular* plaintiff. If the jury answers that question in the negative, liability is almost certain to attach, regardless of the potential impact that the addition of that warning might have on *other* warnings with respect to other risks or on *other* patients' ability or willingness to use the product.

This problem is exacerbated by the case-by-case process of common-law adjudication. Later judges or juries cannot reconsider outcomes reached in earlier cases. Thus, a trier of fact cannot deem unnecessary or inappropriate a warning added in response to an earlier verdict. Nor do judges and juries know how many warnings will be vying for limited reader attention.

That is precisely the role of the FDA. As the Eighth Circuit has emphasized, "[i]t would be difficult for a jury focused on a single case to take into account 'the cumulative, systemic effects' of a series of verdicts. In contrast, the FDA possesses a broader perspective." *Brooks*, 273 F.3d at 797 (quoting Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2175 (2000)). Even where a judge or jury is aware of potential overwarning, it can do little to prevent the problem. *See* James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 302 (1990).

In light of these widely recognized dangers, the FDA has reasonably determined that state-law "product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act." 71 Fed. Reg. at 3934. As the agency summarized in the Preemption Preamble:

> State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public— the central role of FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Id. at 3935. Only comprehensive, exclusive regulation by an expert agency, such as the FDA, can solve the problem of overwarning by permitting an overall evaluation of risk and a rational decision about what risks are sufficiently serious to warrant inclusion on a label, how those warnings should be phrased, and where they should be placed. This is especially true where, as here, the intended readership consists not of ordinary consumers, but, under the learned-intermediary doctrine, highly trained physicians who make judgments based on scientific data and information.

In addition to the danger of overwarning created when states require warnings not approved by the FDA, state regulation via failure-to-warn claims clashes with "the need for national uniformity in product regulation." *Brooks*, 273 F.3d at 797. As the FDA has noted, if judgments under state law were allowed to trump the FDA's assessment of what may appear in drug advertisements, "the public undoubtedly would receive inconsistent information from region to region." *Amicus Curiae* Brief of the United States at 5, *In re*

Paxil Litig., 2002 WL 31375497 (C.D. Cal. Sept. 5, 2002) (No. CV 01-07937 MRP).

This Court has likewise recognized in the context of another federal labeling regime—the Federal Cigarette Labeling and Advertising Act of 1965—that the national economy can be greatly burdened if manufacturers of a product sold around the country are subjected to "diverse, nonuniform, and confusing * * * labeling and advertising regulations." *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 514 (1992). Congress, in the legislative history of the Medical Device Amendments to the FDCA ("MDA"), observed that, "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. REP. NO. 853, 45 (1976) (quoted in *Brooks*, 273 F.3d at 797). For these reasons, it was reasonable for the FDA to conclude that,

> [i]f State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.

71 Fed. Reg. at 3969. Not only would allowing plaintiff's claims to proceed in this case open the door to the burdening of interstate commerce in prescription drugs, but it also would set a precedent that could affect other federally-regulated industries.

B. The decision below misconstrues the FDCA and the relevant regulation promulgated thereunder.

The decision below—which expressly disregards the considered views of the FDA (see Pet. App. 26a)—rests on a fundamental misunderstanding of the FDCA and the relevant

regulation promulgated thereunder. According to the Vermont Supreme Court, plaintiff's failure-to-warn claim does not conflict "with the FDA's labeling requirements for Phenergan because defendant could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation." Pet. App. 6a. The Vermont Supreme Court is mistaken. Its decision rests on a false premise.

Contrary to what the court found, Wyeth was not at liberty to change the Phenergan label after its approval by the FDA. As the dissenting opinion explains, the applicable "regulation does not allow manufacturers to simply reassess and draw different conclusions regarding the same risks and benefits already balanced by the FDA." Pet. App. 40a. See also Pet. 19. Rather, that regulation, 21 C.F.R. § 314.70(c), permits a manufacturer to make a provisional label change *only* if there is newly discovered evidence of a previously unknown or underappreciated risk. As the FDA articulated when proposing § 314.70(c), the rule is designed to "make available important *new* information about the safe use of a drug product." New Drug and Antibiotic Regulations, 47 Fed. Reg. 46622, 46635 (proposed Oct. 19, 1982) (emphasis added). In this case, however, there was no new information. The risks associated with arterial blood exposure to Phenergan were fully known by the FDA when it approved the Phenergan label. See Pet. 6–8. Indeed, in 1997, at the conclusion of a multiyear administrative review of the Phenergan label, the FDA—with specific reference to the risk of "Inadvertent Intra-arterial Injection"—expressly directed Wyeth to "[r]etain [the] verbiage in [the] current label." Pet. App. 162a. Accordingly, Wyeth was not permitted to change the label without prior FDA approval.

As the FDA explained in the Preemption Preamble, the view (adopted by the court below) that "FDA labeling requirements represent a minimum safety standard" that may be augmented by more stringent state-law requirements is a

"misunderstanding" of the FDCA and the regulations promulgated thereunder. 71 Fed. Reg. at 3934. Because "[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health," requirements imposed by the FDA pursuant to the FDCA "establish both a 'floor' and a 'ceiling.'" *Id.* at 3935. Thus, contrary to the decision below, allowing state law to require an additional warning beyond those required by the FDA would "frustrate the agency's implementation of its statutory mandate." *Id.* at 3934.

It would, moreover, place manufacturers in an impossible position. If subject to state-law failure-to-warn claims, drug manufacturers will be forced to add every conceivable warning to their labels or else risk—as in this case—multimillion dollar tort liability. At the same time, however, because "the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act" (71 Fed. Reg. at 3934), adding warnings to drug labels without FDA approval would expose manufacturers to administrative enforcement actions (and even criminal prosecution under 21 U.S.C. §§ 331, 333, 352).[3] In some cases, manufacturers might respond to this dilemma by withdrawing certain products from the market, thereby diminishing in-

[3] Furthermore, in what can fairly be called a Catch-22, adding warnings in response to potential tort liability might even increase a manufacturer's vulnerability to tort claims. As one commentator has suggested, "[i]t seems to be only a matter of time before a plaintiff succeeds in bringing an inadequate warning claim premised on the argument that, although a completely accurate statement of the risk had been provided, the pertinent warning lacked sufficient prominence because it was lost among the clutter of too many other cautionary statements on the label." Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" From the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 379–380 (1994); see also *id.* at 380 n.435 (describing similar cases in various contexts).

terstate commerce and depriving the public of drugs that the FDA had determined to be safe and effective.

II. The Decision Below Conflicts With This Court's Precedent.

The FDA's interpretation of the FDCA is clear: Because state-law failure-to-warn tort claims interfere with the agency's expert determinations as to the proper balance to be struck in drug labels, "FDA approval of labeling under the act * * * preempts conflicting or contrary State law." 71 Fed. Reg. at 3934. In reaching the opposite conclusion, the Vermont Supreme Court acknowledged the FDA's position, but declined to give it any weight, holding that "the FDA's statement deserves no deference." Pet. App. 26a. The Vermont Supreme Court's failure to defer to the FDA's interpretation of the FDCA is contrary to this Court's precedent.

A. The decision below conflicts with this Court's decisions concerning the deference due executive agencies.

Under the Supremacy Clause of the United States Constitution, Congress may preempt state statutory or common law through federal legislation. See U.S. CONST. art. VI, cl. 2; *Chi. & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326–327 (1981). It is well settled that federal regulations implementing such statutes "have no less pre-emptive effect than federal statutes" themselves. *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982).

In the course of delineating the circumstances in which preemption exists, this Court has held that a federal statute or regulation impliedly preempts any state law (including any state common law) that would "prevent or frustrate the accomplishment of a federal objective." *Geier*, 529 U.S. at 873–874; see also *Locke*, 529 U.S. at 109 (preemption is implied "when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress") (internal quotation marks and citation omitted).

When, as in the case of the FDA, Congress has delegated authority to an expert federal agency to implement and enforce a federal regulatory scheme, the agency's determination that state law threatens to upset federal objectives "is dispositive * * * unless either the agency's position is inconsistent with clearly expressed congressional intent, * * * or subsequent developments reveal a change in that position." *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 714–715 (1985) (citation omitted).

This deference to an agency's interpretation of the preemptive scope of a federal statute or regulation that the agency administers derives from the seminal decision in *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). As the Court explained in *Chevron*, administrative deference inheres in the congressional decision to delegate powers to the agency:

> The power of an administrative agency to administer a congressionally created * * * program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress. If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. *In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.*

Id. at 843–844 (citations and internal quotation marks omitted; emphasis added). Thus, under *Chevron*, "a court must give effect to an agency's regulation containing a reasonable interpretation of an ambiguous statute." *Christensen* v. *Har-*

ris County, 529 U.S. 576, 586–587 (2000). That same absolute deference is accorded to "an agency's [reasonable] construction of its own regulations." *Martin* v. *Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 150 (1991) (citation omitted).

In this instance, the FDA is, pursuant to the FDCA, "the expert Federal agency responsible for evaluating and regulating drugs." 71 Fed. Reg. at 3935. See also 21 U.S.C. § 393(b)(2)(B) (the FDA is to ensure that "human * * * drugs are safe and effective"). As such, it has adopted—in the Preemption Preamble and numerous *amicus* briefs (see *supra* at 1 n.2)—an authoritative interpretation of the FDCA and the agency's own regulations according to which "FDA approval of labeling under the act * * * preempts conflicting or contrary State law." 71 Fed. Reg. at 3934. That determination—based on the agency's recognition that state-law failure-to-warn claims interfere with its ability to implement finely calibrated labeling decisions under the FDCA—is reasonable, and entitled to full deference.

The fact that the FDA has articulated its preemption determination in a regulatory preamble and a series of *amicus* briefs does not diminish the deference owed that determination. As this Court recognizes, an agency's conclusion that federal law preempts state law may properly be communicated in "regulations, *preambles*, interpretive statements and responses to comments." *Hillsborough County*, 471 U.S. at 718 (emphasis added). Similarly, the fact that the "agency's fair and considered judgment on the matter in question" is conveyed "in the form of a legal brief" does not make the agency's view "unworthy of deference." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997). See also *Geier*, 529 U.S. at 883 (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties).

It was, therefore, contrary to this Court's precedent for the Vermont Supreme Court to disregard the FDA's authori-

tative determination that FDA approval of a drug label preempts state-law tort claims premised on the manufacturer's failure to provide a warning not required by the FDA.

B. The decision below conflicts with this Court's decisions concerning the effect of savings clauses on implied preemption.

The Vermont Supreme Court's erroneous failure to defer to the FDA's interpretation of the FDCA rests, in part, on that court's misunderstanding of this Court's preemption jurisprudence.

Recognizing that "deference to an agency's interpretation is appropriate only when a statute is 'silent or ambiguous with respect to the specific issue' the agency has considered," Pet. App. 25a (quoting *Chevron*, 467 U.S. at 842–843), the Vermont Supreme Court disregarded the FDA's interpretation of the FDCA because, in that court's opinion, (a) drug manufacturers can add warnings required by state common-law standards on their own initiative without violating federal regulations, and (b) Congress, in a savings clause, expressly limited implied preemption in the drug context to situations in which compliance with federal and state law is a physical impossibility. See Pet. App. 21a, 26a–28a. But neither premise is correct. The first rests on the court's misunderstanding of 21 C.F.R. § 314.70(c), which—contrary to the decision below—does *not* give drug manufacturers the power to add warnings unilaterally absent new, scientifically valid information. See *supra* at 11. The second rests on the court's misinterpretation of this Court's implied preemption doctrine.

Section 202 of the 1962 amendments to the FDCA provides that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law * * * unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962 § 202, Pub. L. 87-781, 76 Stat. 780, 793 (1962). In the eyes

of the Vermont Supreme Court, this provision "remove[d] from [its] consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress." Pet. App. 21a. That conclusion, however, is contrary to this Court's precedent.

As this Court made clear in *Geier*, "'conflicts' that prevent or frustrate the accomplishment of a federal objective and 'conflicts' that make it 'impossible' for private parties to comply with both state and federal law" are equally repugnant to the Supremacy Clause. 529 U.S. at 873. Accordingly, this Court has steadfastly "refused to read general 'saving' provisions"—such as Section 202—"to tolerate actual conflict *both* in cases involving impossibility *and* in 'frustration-of-purpose' cases." *Id.* at 874 (citations omitted). Because any form of conflict between federal and state law is intolerable to the Supremacy Clause, this Court rejects "attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants preemption in a particular case." *Ibid.*

That, however, is precisely what the Vermont Supreme Court did below. It interpreted Section 202 as abrogating state law only when simultaneous compliance with federal law is impossible, but as preserving state law even if it "present[s] an obstacle to the purposes and objectives of Congress." Pet. App. 21a. Neither the Supremacy Clause nor this Court's precedent permits such a result.[4]

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[4] Notably, the language used by Congress in Section 202 to describe which state laws are preempted—namely state laws that are in "direct and positive conflict" with federal law—is identical to that used by this Court in *Sinnot* v. *Davenport*, 63 U.S. (22 How.) 227, 243 (1859). In that case, this Court held that a state law, which imposed a registration requirement on steamboats beyond that imposed by a federal law meant to facilitate interstate transport, was preempted *even though simultaneous compliance with both state and federal law was not impossible*. Thus, *Sinnot* makes clear that the phrase "direct and positive conflict" encompasses

III. This Case Is An Appropriate Vehicle For Resolving A Recurring Conflict In The Lower Courts On An Important Issue Of Federal Statutory Interpretation.

A. Certiorari should be granted in this case.

As acknowledged by both the majority and dissenting opinions below (see Pet. App. 11a–13a; Pet. App. 23a; Pet. App. 39a n.7; see also Pet. 16–17), the lower courts are deeply divided on whether the FDCA preempts state-law tort claims alleging that an FDA-approved drug label failed to provide adequate warning. Compare, *e.g.*, *Sykes* v. *GlaxoSmithKline*, 2007 WL 957337 (E.D. Pa. Mar. 28, 2007) (notice of appeal filed Mar. 29, 2007) (holding state-law failure-to-warn claims preempted); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (same); *Needleman* v. *Pfizer, Inc.*, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004) (same); *Dusek* v. *Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) (same); *Ehlis* v. *Shire Richwood, Inc.*, 233 F. Supp. 2d 1189 (D.N.D. 2002) (same), aff'd on other grounds, 367 F.3d 1013 (8th Cir. 2004); with, *e.g.*, *Laisure-Radke* v. *Par Pharm., Inc.*, 2006 WL 901657 (W.D. Wash. Mar. 29, 2006) (holding state-law failure-to-warn claims not preempted); *Peters* v. *Astrazeneca, LP*, 417 F. Supp. 2d 1051 (W.D. Wis. 2006) (same); *Cartwright* v. *Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005) (same); *Zikis* v. *Pfizer, Inc.*, 2005 WL 1126909 (N.D. Ill. May 9, 2005) (same); *Witczak* v. *Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005) (same); *Caraker* v. *Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001) (same); *Mazur* v. *Merck & Co.*, 742 F. Supp. 239 (E.D. Pa. 1990) (same).[5] Indeed, one recent decision—holding, contrary to

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situations in which state law, although not physically incompatible with federal law, nonetheless impedes attainment of the federal statutory objective.

[5] As noted by the FDA in the Preemption Preamble, the Vermont Supreme Court is not the only lower court to have mistakenly con-

the decision below, that state-law tort claims such as those brought by plaintiff are impliedly preempted under the FDCA—expressly recognizes the "many conflicting court decisions on this topic." *Colacicco* v. *Apotex, Inc.*, 432 F. Supp. 2d 514, 518 (E.D. Pa. 2006), appeal docketed, No. 06-3107 (3d Cir. June 21, 2006). See also *McNellis* v. *Pfizer, Inc.*, 2006 WL 2819046, at *12 (D.N.J. Sept. 29, 2006) (reaffirming decision holding that state-law failure-to-warn claims are not preempted but certifying issue for interlocutory appeal given acknowledged "split in authority"), appeal docketed, No. 06-5148 (3d Cir. Dec. 27, 2006).

The question of FDCA preemption is an extremely important one. It directly affects tens of thousands of cases that are currently pending. See Pet. 13 n.4. Moreover, it implicates substantial policy issues affecting both public health and interstate commerce (in the pharmaceutical industry and beyond). See *supra* at 4–10.

Although there is, as of yet, no circuit split on the issue, this Court should not delay its resolution of the deep division below. Given, on the one hand, the clearly erroneous decision of the Vermont Supreme Court, and, on the other hand, the compelling arguments in favor of preemption, a conflict between a state court of last resort and a United States court of appeals on this important federal question seems highly likely, if not inevitable, as the many pending cases percolate upwards. Awaiting the probable circuit split before deciding the issue would have deleterious consequences: Courts will be burdened with large numbers of cases that should never have been filed, let alone allowed to go to trial; pharmaceuti-

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strued FDA drug labeling requirements as setting only a floor, but not a ceiling, for state regulation of pharmaceuticals. See 71 Fed. Reg. at 3934–3935 (citing, *inter alia*, *Brochu* v. *Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981); *Salmon* v. *Parke-Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975); *In re Tetracycline Cases*, 747 F. Supp. 543 (W.D. Mo. 1989)).

cal manufacturers will be caught in an inescapable dilemma, forced to choose between complying with federal law and complying with conflicting state law; and the public health will be endangered as juries impose unsubstantiated warnings that obscure valid warnings and possibly deter patients from accepting effective treatments.

This case presents the Court with an ideal vehicle for resolving the persistent conflict over FDCA preemption of state-law tort claims. The judgment below depends entirely on the resolution of the federal statutory question. There is no independent state ground to sustain the judgment below if this Court holds that plaintiff's tort claims are preempted under the FDCA. Furthermore, this case presents a factual record devoid of the confounding issues that often afflict similar cases. There is, for example, no evidence or allegation that Wyeth concealed information from the FDA or failed to comply with FDA regulations when obtaining FDA approval of the Phenergan label. Moreover, after a multiyear review that addressed the danger of inadvertent intra-arterial injection in particular, the FDA specifically directed Wyeth to retain the Phenergan label.

B. At minimum, this Court should call for the views of the Solicitor General.

In an effort to avoid and correct erroneous decisions such as that below, the FDA has filed numerous *amicus* briefs in courts around the country. See *supra* at 1 n.2. If asked, the federal government would likely be eager to offer this Court its expert opinion on the scope of implied preemption under the FDCA as well as whether review of the issue is warranted. Accordingly, given the deep division in the lower courts and the tremendous importance of the issue presented, it would be appropriate for this Court, at minimum, to call for the views of the Solicitor General in this case.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APRIL 2007

APPENDIX

APPENDIX A

Corporate Members of the Product Liability Advisory Council (as of April 2, 2007)

3M
A.O. Smith Corporation
Altec Industries
Altria Corporate Services, Inc.
American Suzuki Motor Corporation
Amgen Inc.
Andersen Corporation Anheuser-Busch Companies
Appleton Papers, Inc.
Arai Helmet, Ltd.
Astec Industries
BASF Corporation
Bayer Corporation
Bell Sports
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Briggs & Stratton Corporation
Brown-Forman Corporation
CARQUEST Corporation

Caterpillar Inc.
Chevron Corporation
Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation
DaimlerChrysler Corporation
The Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Ford Motor Company
Freightliner LLC
Genentech, Inc.
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Guidant Corporation
Harley-Davidson Motor Company The Heil Company
Honda North America, Inc.
Hyundai Motor America
ICON Health & Fitness, Inc.
Illinois Tool Works, Inc.

International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jarden Corporation
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Koch Industries
Kolcraft Enterprises, Inc.
Komatsu America Corp.
Kraft Foods North America, Inc.
Lincoln Electric Company
Magna International Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Mercedes-Benz of North America, Inc.
Merck & Co., Inc.
Michelin North America, Inc.
Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Nokia Inc.
Novartis Consumer Health, Inc.
Novartis Pharmaceuticals Corporation
Occidental Petroleum Corporation
PACCAR Inc.

Panasonic
Pfizer Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Purdue Pharma L.P.
Putsch GmbH & Co. KG
The Raymond Corporation
Raytheon Aircraft Company
Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Sanofi-Aventis
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive
UST (U.S. Tobacco)
Vermeer Manufacturing Company

The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Water Bonnet Manufacturing, Inc.
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.